UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF WASHINGTON
AT SEATTLE

CHRISTOPH BOLLING, et al., Plaintiffs, v. DENDREON CORPORATION, et al., Defendants.	CASE NO. C13-0872JLR ORDER GRANTING IN PART AND DENYING IN PART MOTION TO DISMISS

I. INTRODUCTION

Before the court is a motion to dismiss this securities fraud case pursuant to Federal Rule of Civil Procedure 12(b)(6). (Mot. (Dkt. # 61).) The motion is brought by Defendants Dendreon Corporation ("Dendreon" or "Company") and several of its corporate officers, Mitchell H. Gold, Gregory T. Schiffman, and Hans E. Bishop (collectively "Defendants"). (*See id.*) Dendreon is a Seattle-based biotechnology firm that makes a prostate cancer treatment called Provenge. (*See* Am. Compl. (Dkt. # 32)

¶ 35.) Plaintiffs are roughly 30 Dendreon investors who claim to have been harmed by an extensive fraud related to Provenge. (*See generally* Am. Compl.)

This is the second motion to dismiss in this case. Previously, the court dismissed several of Plaintiffs' securities fraud claims against Defendants—notably all of Plaintiffs' federal claims—but allowed several state law claims to proceed. (1/28/14 Order (Dkt. # 54).) The court also granted Plaintiffs leave to amend their complaint. (*Id.* at 33.) Shortly thereafter, Plaintiffs filed a Second Amended Complaint detailing additional allegations against Defendants. (2d Am. Compl. (Dkt. # 55).)[1] Defendants now move to dismiss that complaint in its entirety. (Mot.)

Plaintiffs' Second Amended Complaint changes the analysis on this second motion to dismiss, but not the result. The new complaint narrows the scope of Plaintiffs' allegations against Dendreon and its corporate officers. (*See generally* 2d Am. Compl.) In particular, Plaintiffs' amended complaint focuses its fraud allegations on Defendants' statements and omissions regarding (1) physician reimbursement; (2) capacity constraints; and (3) whether Dendreon was "on track" to meet its revenue guidance and other forecasts. (*See id.*) The newly-refined complaint contains more detail with respect to these allegations, including allegations about board meeting presentations that relate directly to what Defendants knew and when. (*See, e.g.*, *id.* ¶¶ 63, 69, 70.) Nevertheless,

[1] There are two copies of the Second Amended Complaint before the court—a clean copy and a redline. (*See* Dkt. ## 55, 73.) In places, the paragraphs are numbered slightly different as between the two documents. For simplicity, the court will cite to the paragraph numbers found in the redlined version of the complaint, which is the more recently-filed of the two. This makes no difference in the court's analysis.

these new allegations do not cure the basic defect that plagued the original complaint: namely, Plaintiffs have not established a strong inference of scienter. (*See* 1/28/14 Order at 22-28.) As such, the result of this motion is the same as the previous motion. As described in more detail below, the court GRANTS in part and DENIES in part Defendants' motion, dismissing the federal claims but allowing the same state law claims as before to proceed.

II. BACKGROUND

Plaintiffs are 30 investors who purchased or otherwise acquired Dendreon's publicly-traded securities between April 29, 2010, and August 3, 2011 ("the relevant period"). (Am. Compl. ¶¶ 13-32.) Plaintiffs assert claims against Dendreon, its Chairman and former Chief Executive Officer Mr. Gold, its former Chief Operating Officer, Mr. Bishop, and its Chief Financial Officer, Mr. Schiffman, for violations of Sections 10(b), 20(a) and 20A of the Securities Exchange Act of 1934, and common law fraud and negligent misrepresentation. (*See id.* ¶¶ 159-206; 2d Am. Compl. ¶¶ 211-58.)

Dendreon is a biotechnology company that makes one product: Provenge. (*Id.* ¶ 43.) Provenge is a treatment for advanced prostate cancer. (*Id.*) Dendreon developed Provenge over a fifteen-year period at a cost of over $1 billion. (*Id.* ¶ 45.) On April 29, 2010, after 15 years of research, Dendreon announced that the company had secured Food and Drug Administration ("FDA") approval for Provenge. (*See id.* ¶ 45.)

Provenge is a unique product. It is a first-in-class immunotherapy that, in effect, trains a patient's immune system to fight prostate cancer. (*Id.* ¶ 44.) During treatment, cells from a patient's immune system are taken from the patient's body, cultured and

processed to strengthen their resistance to cancer, then put back in the patient's body. (*Id.*) No other prostate cancer treatment works in this way. Even the manufacturing process is unique: First, doctors collect the patient's cells by drawing blood at an approved "apheresis" site and immediately ship the cells to a Dendreon manufacturing facility for processing. (*Id.* ¶ 46.) Processing must begin within 18 hours of collection or the cells will no longer be viable. (*Id.*) After Dendreon has completed production of a dose of Provenge, the company must again contend with strict deadlines; if the medicine is not infused into the patient within 18 hours, the cells will die. (*Id.*)

Notably, Dendreon sells Provenge through a "buy-and-bill" reimbursement model. (*Id.* ¶ 47, 102.) Under this model, the treating physician makes an up-front payment for Provenge then later seeks reimbursement from the patient's private insurer or from Medicare. (*Id.*) As a result, the physician could be responsible for the entire cost of the treatment if the patient's insurer ultimately refuses to provide reimbursement for Provenge. (*Id.*) Each Provenge infusion costs $31,000.00. (*Id.* ¶ 47.) A full treatment consists of three infusions over a one-month period for a total cost of $93,000.00. (*Id.*)

Dendreon announced on April 29, 2010, that Provenge had been approved by the FDA and would soon be commercially available. (*See id.* ¶ 45.) In the same announcement, however, Dendreon emphasized that it would launch the drug only gradually. (*Id.*) During the first phase of the drug's launch, Provenge would be made available at only the 50 institutions and physician groups that had participated in the clinical trials for the drug. (8/9/13 Wechkin Decl. (Dkt. # 39) Ex. 1 at 5.) The reason for this was Dendreon's complex manufacturing process and the reality that Provenge could

be produced at only a limited number of Dendreon processing facilities, each of which had to be approved by the FDA before use. (*See id.*) For this reason, the company told the public and investors that demand for Provenge would exceed Dendreon's ability to supply it for the first 12 months after the product was introduced into the market. (Am. Compl. ¶¶ 60-64.) Nevertheless, Dendreon claimed that it expected to have capacity to treat, and was "on track" to treat, 2,000 patients over the 12 months following FDA approval. (8/9/13 Wechkin Decl. Ex. 1 at 5, 9.) In the announcement, Mr. Gold, who was President of Dendreon at that time, described Provenge as "the Holy Grail of Oncology." (*Id.* Ex. 1 at 2; *see* Am. Compl. ¶ 61.) Dendreon's shares rose 36.1 % following the announcement. (Am. Compl. ¶ 63.)

Dendreon began selling Provenge in May 2010. Over the next six months, Dendreon reported revenue of $350,000.00 in May, $2.45 million in June, $5.2 million in July, $7.2 million in August, $7.8 million in September, and $9.5 million in October 2010. (8/9/13 Wechkin Decl. Ex. 2 at 3-4, Ex. 16.)

Initially, sales did not meet expectations, but investors' hopes for Provenge remained high. On August 3, 2010, Dendreon announced second quarter sales of $2.8 million, of which $2.45 million was generated in June 2010. (*Id.* Ex. 2 at 3; Am. Compl. ¶ 68.) Plaintiffs allege that this figure was 57 % less than Wall Street's expectation of $4.4 million. (Am. Compl. ¶ 68.) Dendreon stated that it was seeing "strong demand in the clinics . . . currently providing Provenge," and that "the majority of our centers tell us that they have waiting lists." (8/9/13 Wechkin Decl. Ex. 2 at 10-11, 15-16, 18.) Dendreon also stated that "certain sites . . . have very active and . . . very long waiting

lists and others . . . are perhaps in a different situation." (*Id.* Ex. 2 at 16-17.) Dendreon also reiterated its guidance for treating approximately 2,000 patients over the first 12 months. (*Id.* at 4-5; *see also id.* at 10 ("[W]e expect to treat about 2,000 patients over the first 12 months, we're on track with that.").)

In addition, on August 3, 2010, Dendreon advised the market about a new regulatory development. On June 30, 2010, the Centers for Medicare and Medicaid Services announced that they were undertaking a National Coverage Analysis ("NCA") for Provenge. (*Id.* Ex. 2 at 4.) The outcome of that process would be a National Coverage Determination ("NCD"), which all local Medicare contractors would be obliged to follow. (*Id.*) Until the NCA was complete, however, coverage decisions had to be made individually by each of the country's 15 regional Medicare administrators. (*See id.* at 4-5.) Dendreon reported its progress with these administrators over the next months, and securities analysts closely tracked the issue. (*Id.* Ex. 2 at 4; *id.* Ex. 3 at 4-5.)

On November 3, 2010, Dendreon provided revenue guidance for the first time and reiterated that demand for Provenge was strong. (*See id.* Ex. 3.) Dendreon projected 2010 revenues of approximately $46-$47 million, with $23-$24 million occurring in the fourth quarter of 2010. (*Id.* Ex. 3 at 2.) In addition, Dendreon projected 2011 revenue of $350-$400 million, with half of those revenues occurring in the fourth quarter of 2011. (*Id.* Ex. 3 at 3, 7.) Dendreon also stated that it "continue[d] to see strong demand across

the majority of the country with most sites having waiting lists."[2] (*Id.* Ex. 3 at 3-4.) The company reminded investors of its "limited capacity," but stated that it was "on track with the expansion of [the] New Jersey facility as well as the completion of facilities in Atlanta and L[os] A[ngeles], for which construction is substantially complete . . . ." (*Id.* Ex. 3 at 4.) Although demand was "exceeding [its] ability to supply the market," Dendreon explained that it expected this issue to "be resolved, once additional capacity comes online from New Jersey, Atlanta, and L[os] A[ngeles] next year" and that revenues would increase accordingly. (*Id.* at 11-12.)

In early 2011, Dendreon appeared to be on track to meet its revenue guidance, and continued to tout strong demand for Provenge. On January 7, 2011, Dendreon announced anticipated sales of $25 million for the fourth quarter of 2010. (Am. Compl. ¶ 82.) Mr. Gold stated that "demand for Provenge is robust," and maintained that sales for Provenge remained low only because "we're still in this capacity constrained environment." (*Id.*) On March 1, 2011, Dendreon reported 2010 revenue of approximately $48 million, of which $25 million occurred in the fourth quarter. (*Id.* ¶ 83; 8/9/13 Wechkin Decl. Ex. 5 at 3.) These results were consistent with the company's public revenue guidance. Dendreon reiterated its $350-$400 million revenue guidance for 2011 and shared the model behind the guidance. (*Id.*) The projected revenue figure could be derived by

---

[2] Dendreon reiterated its confidence about demand several times, stating: "We are not at all worried about demand," "[w]e're seeing very solid demand this year," "we're confident that demand will stay strong throughout next year," and "clearly the demand out there is exceeding our ability to supply the market." (Wechkin Decl. Ex. 3 at 8, 10.)

multiplying the number of medical practices expected to be enrolled by the number of patients each practice was expected to generate. (*Id.* Ex. 5 at 4.)

Meanwhile, Dendreon was busily completing additional workstations. Dendreon announced on March 1, 2011, that it had completed construction of its expanded production capacity in New Jersey and that the FDA was expected to decide whether to approve the new space shortly. (*Id.*) Ten days later, the FDA approved the 36 new workstations in Dendreon's New Jersey plant. (*Id.* Ex. 6 at 3.)

Dendreon remained on track through the first quarter of 2011. On May 2, 2011, Dendreon announced revenues of $28 million for the first quarter of 2011, which were consistent with its original capacity estimate of $9-$10 million per month for that quarter. (*Id.* Ex. 6 at 3, 6.) Dendreon also announced April 2011 revenues of $15 million and addressed concerns about demand. (*Id.* Ex. 6 at 3.) Mr. Gold stated that although there were parts of the country where waiting lists still existed, since Dendreon had brought on new capacity "it's a much less significant problem than it was during the first part of [Provenge's] launch." (*Id.* Ex. 6 at 13.)

Other positive developments followed. In June 2011, the FDA approved the company's second plant in Los Angeles, which included 36 additional workstations. (*Id.* Ex. 12.) In addition, one year after initiating the NCA, the Centers for Medicare and Medicaid Services announced a favorable NCD. (*Id.*) The effect of the NCD was to standardize Medicare and Medicaid reimbursement processes across the country. (*Id.*) Provenge was issued a "Q-code," which allows physicians to submit claims electronically, accelerating the time to payment. (*Id.*)

Despite this run of positive news, there was trouble ahead for Dendreon. On August 3, 2011, Dendreon announced second quarter revenue of approximately $51 million and July sales of approximately $19 million. (8/9/13 Wechkin Decl. Ex. 7 at 3.) These figures represented large gains over previous revenue totals, but they still fell short of expectations. Specifically, they fell short of the trajectory needed to meet Dendreon's revenue guidance. (*Id.*) It seemed Provenge was not catching on as fast as Dendreon had anticipated and, as a result, Dendreon withdrew its revenue guidance. (*Id.*)

Dendreon explained the cause of the problem. It explained that physicians were not prescribing Provenge at the rate Dendreon had anticipated. (*Id.* Ex. 7 at 3-7, 11-12.) Worse, Dendreon executives believed the problem would persist in the near-term. (*Id.*) Dendreon further explained that the model that supported its revenue guidance—number of in-serviced sites multiplied by number of patients expected per site—had been partially inaccurate. Although the number of in-serviced sites was higher than expected,[3] the sites had not generated the expected one to two prescriptions per month. (*Id.* Ex. 7 at 3-4.) Instead, they were generating only 0.8 prescriptions per month. (*Id.*) Dendreon explained that it believed that some physicians were reluctant to have multiple patients on Provenge at the same time because of the drug's up-front cost of $93,000.00 for the three-infusion course of treatment. (*Id.* at 4.) On the brighter side, Dendreon predicted

[3] Dendreon had forecast 225 sites at the end of the second quarter, but there were in fact 255 sites at that point and 300 by the end of July. (Wechkin Decl. Ex. 6 at 2.)

that with a favorable NCD and Q-code now on the books, improvement would soon follow. (*See id.*) This small patch of bright news was not enough.

Dendreon's stock price dropped steeply following the August 3, 2011, announcement. (*See* Am. Compl. ¶ 140.) On the first full day of trading after the announcement, the price of Dendreon's stock fell 67 %, from $35.84 to $11.69. (*Id.*) This represented a loss of over $3.5 billion in market capitalization and "the biggest single day decline since the company's initial public offering in June 2000." (*Id.*)

Following the drop in Dendreon's stock price on August 3, 2011, numerous class action complaints alleging securities fraud against Dendreon and its various officers were filed in this court. (*See Frias, et al. v. Dendreon, et al.*, No. C11-1291JLR.) The plaintiffs in those actions asserted that Defendants made false and misleading statements and omissions during the relevant period that deceptively reassured investors that Dendreon remained a good investment. The court consolidated the actions and scheduled oral argument on a motion to dismiss. (*See id.*, 12/19/11 Order (Dkt. # 50); *id.* Dkt. ## 93-94.) However, before the court could rule on the motion, the parties settled. (*See id.* 4/24/13 Stip. (Dkt. # 97).)

Plaintiffs in this case are individuals who opted out of the class action settlement in the prior case. In their original complaint, they brought claims based on factual allegations that are materially similar to those made in the class action complaints. (*Compare id.* Compl. (Dkt. # 1) *with* Am. Compl.) In particular, Plaintiffs alleged that Defendants made false and misleading statements or omissions concerning (1) the high level of demand for Provenge, (2) Dendreon's capacity constraints with respect to the

production of Provenge (*see* Am. Compl. ¶¶ 60-101), (3) the lack of physician concern about the Company's "buy-and-bill" reimbursement structure (*see id.* ¶¶ 102-13), (4) Dendreon's market guidance that it would treat 2,000 patients in the first 12 months after launch and (5) Dendreon's 2011 revenue guidance (*see id.* ¶¶ 114-29).

Defendants moved to dismiss the complaint, and the court largely granted the motion. (1/28/14 Order.) First, the court held that Plaintiffs' claims based on forward-looking revenue guidance and patient-treatment predictions were barred by the "safe harbor" for forward-looking statements found in the Private Securities Litigation Reform Act ("PSLRA"), 15 U.S.C. § 78u-4. (1/28/14 Order at 15-21.) Second, for the other federal claims, the court held that Plaintiffs did not adequately plead a strong inference of scienter as required under the PSLRA. (*Id.* at 22-28.) The court conducted a "holistic" analysis as required by the PSLRA, concluding that the inference of scienter was not as compelling as the competing inference that Defendants simply misjudged the level of demand for Provenge. (*Id.*) Third, the court dismissed one of Plaintiffs' state law claims for failure to properly plead the elements of the claim, but denied Defendants' motion to dismiss with respect to all other state law claims, reasoning that those claims were not subject to the stringent analysis required by the PSLRA. (*Id.* at 28-32.) Finally, the court granted Plaintiffs 20 days to amend their complaint to cure the defects identified in the order. (*Id.* at 33.)

Plaintiffs amended their complaint, and Defendants now move to dismiss the Second Amended Complaint. (*See* Mot.)

III. ANALYSIS

A. Standard on a Motion to Dismiss in a Securities Fraud Case

A motion to dismiss in a securities fraud case is subject to three layers of analysis. First, the court must examine the pleadings under ordinary Rule 12(b)(6) standards: "courts must, as with any motion to dismiss for failure to plead a claim on which relief can be granted, accept all factual allegations in the complaint as true." *Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308, 322 (2007). However, as is ordinarily the case, the court need not "accept as true allegations that contradict matters properly subject to judicial notice or by exhibit" or "allegations that are merely conclusory, unwarranted deductions of fact, or unreasonable inferences." *In re Gilead Sciences Sec. Litig.*, 536 F.3d 1049, 1055 (9th Cir. 2008).

Second, the court must examine the pleadings for compliance with the particularized pleading requirement found in Federal Rule of Civil Procedure 9(b). *Zucco Partners, LLC v. Digimarc Corp.*, 552 F.3d 981, 990 (9th Cir. 2009). The Ninth Circuit has long applied the heightened pleading standard of Rule 9(b) to securities fraud complaints, *see id.* (citing *Semegen v. Weidner*, 780 F.2d 727, 729, 734-35 (9th Cir. 1985)), and therefore requires the element of falsity, or "a material misrepresentation or omission of fact," to be pled with particularity, *see id.* (citing *Ronconi v. Larkin*, 253 F.3d 423, 429 n.6 (9th Cir. 2001)).

Last, the court must examine the pleadings under the PSLRA. Since 1995, courts have been required to scrutinize securities fraud complaints under the more exacting standards of the PSLRA. The PSLRA amended the Securities Exchange Act to require

that a securities fraud complaint "plead with particularity both falsity and scienter." *Zucco*, 552 F.3d at 990 (quoting *Ronconi*, 253 F.3d at 429). To properly allege falsity, a securities fraud complaint must now "specify each statement alleged to have been misleading, [and] the reason or reasons why the statement is misleading." 15 U.S.C. § 78u-4(b)(1). To the extent that an allegation regarding a statement or omission is made on information and belief, "the complaint shall state with particularity all facts on which that belief is formed." *Id*. In doing so, the plaintiff must "reveal 'the sources of [his] information.'" *In re Daou Sys., Inc. Sec. Litig.*, 411 F.3d 1006, 1015 (9th Cir. 2005).

The PSLRA has even more exacting requirements for alleging scienter. To properly allege scienter, the plaintiff must "state with particularity facts giving rise to a strong inference that the defendant acted with the required state of mind." 15 U.S.C. § 78u–4(b)(2). In other words, the plaintiff must plead with particularity the facts evidencing "the defendant's intention 'to deceive, manipulate, or defraud.'" *Tellabs*, 551 U.S. at 313 (quoting *Ernst & Ernst v. Hochfelder*, 425 U.S. 185, 194 (1976)). To satisfy the PLSRA's rigorous pleading standards, the complaint's scienter allegations must give rise not just to a plausible inference of scienter, but to an inference that is "cogent and at least as compelling as any opposing inference of nonfraudulent intent." *Id.* at 314; *see also id.* at 324.

This last part is very different from the ordinary Rule 12(b)(6) standard. On an ordinary Rule 12(b)(6) motion, the court indulges all reasonable inferences in the plaintiff's favor. *See Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atlantic Corp v. Twombly*, 550 U.S. 544, 570 (2007)). Under the PSLRA, the court must weigh

competing inferences and "only allow the complaint to survive a motion to dismiss if the malicious inference is at least as compelling as any opposing inference." *Zucco*, 552 F.3d at 991. Thus, a "Rule 10b-5 claim does not receive the traditional deference a court affords a complaint in resolving a motion to dismiss for failure to state a claim." *In re Watchguard Sec. Litig.*, No. C05-0678JLR, 2006 WL 2038656, at *3 (W.D. Wash. Apr. 21, 2006).

B. Materials the Court Considers

In deciding this motion, the court is not strictly limited to the confines of the complaint. The court can also consider documents that are attached to the complaint or that are judicially noticeable. *Tellabs*, 551 U.S. at 322. In the previous motion, the court considered numerous documents that formed the basis of Plaintiff's complaint but that were not attached to the complaint. (*See* 1/28/14 Order at 13-14.) Defendants provided these documents in response to the allegations in the complaint, which directly relied on the documents, but which Plaintiffs had not provided. (*See id.*) Defendants also provided several documents that were on file with the SEC and were therefore judicially noticeable. (*See id.*) The court relied on these documents in its ruling, citing the "incorporation by reference" doctrine. (*Id.*)

In ruling on the present motion, the court again relies on the incorporation by reference doctrine. Under that doctrine, when ruling on a Rule 12(b)(6) motion to dismiss a § 10(b) action, a court must consider the complaint in its entirety, including "documents incorporated into the complaint by reference, and matters of which a court may take judicial notice." *Tellabs*, 551 U.S. at 322. Where a plaintiff fails to attach to

the complaint the documents upon which the complaint is premised, a defendant may attach such documents in order to show that they do not support the plaintiff's claim. *E.g.*, *In re Pac. Gateway Exch., Inc.*, 169 F. Supp. 2d 1160, 1164 (N.D. Cal. 2001). The court may also take judicial notice of public filings, such as those made with the SEC. *Dreiling v. Am. Exp. Co.*, 458 F.3d 942, 946 n.2 (9th Cir. 2006) (stating that the court "may consider documents referred to in the complaint or any matter subject to judicial notice, such as SEC filings.") (citing *MGIC Indem. Corp. v. Weisman*, 803 F.2d 500, 504 (9th Cir. 1986)). In support of their motion, Defendants have submitted many of the same documents as before, but also several new documents. (*See* 3/24/14 Wechkin Decl. (Dkt. # 62).)

The new documents are properly before the court. The new documents consist primarily of presentation slides from Dendreon board meetings. (*See, e.g.*, *id.* Exs. 15-22.) Plaintiffs' Second Amended Complaint is directly premised on the information contained in these documents. (*See, e.g.*, 2d Am. Compl. 63, 69, 70.) The Second Amended Complaint relies heavily on quotations and other information from these presentation slides to demonstrate an inference of scienter. (*See id.*) Indeed, the inclusion of information from these slides is the single biggest substantive revision contained in the Second Amended Complaint. Thus, it is appropriate for the court to consider these documents under the incorporation by reference doctrine because the complaint is premised on them and Plaintiffs have not attached them. *See In re Pac. Gateway*, 169 F. Supp. at 1164. As such, Defendants' motion does not need to be

converted into a motion for summary judgment pursuant to Federal Rule of Civil Procedure 12(d). *See id.*; (Resp. at 13-16.)

C. Securities Fraud Claims Under Section 10(b)

Section 10(b) of the Securities Exchange Act of 1934 makes it unlawful for "any person . . . [t]o use or employ, in connection with the purchase or sale of any security registered on a national securities exchange . . . any manipulative or deceptive device or contrivance in contravention of such rules and regulations as the Commission may prescribe as necessary or appropriate in the public interest or for the protection of investors." 15 U.S.C. § 78j(b). One such rule promulgated under the Act is SEC Rule 10b–5, which provides, inter alia, that "[i]t shall be unlawful for any person . . . [t]o engage in any act, practice, or course of business which operates or would operate as a fraud or deceit upon any person, in connection with the purchase or sale of any security." 17 C.F.R. § 240.10b–5(c). To prevail on a Rule 10b-5 claim, a securities fraud plaintiff must prove five elements: "'(1) a material misrepresentation or omission of fact, (2) scienter, (3) a connection with the purchase or sale of a security, (4) transaction and loss causation, and (5) economic loss.'" *Zucco*, 552 F.3d at 990 (quoting *In re Daou*, 411 F.3d at 1014).

D. Differences Between Previous Complaint and Second Amended Complaint

As noted above, there are several salient differences between Plaintiffs' previous complaint and the Second Amended Complaint. Principally, the new complaint narrows the scope of the claims to three primary groups of allegations—those related to (1) physician reimbursement concerns, (2) capacity constraints, and (3) "on-track"

statements. In addition, the new complaint adds details with respect to some of these claims. In other places, the new complaint simply restructures allegations or recasts them in a different light without adding any new factual content. The court addresses, in turn, amendments relating to each of Plaintiffs' primary groups of allegations.

1. Physician Reimbursement Concerns

In their new complaint, Plaintiffs heavily emphasize their "physician reimbursement concerns" claim. Indeed, they make this claim a major focal point of their amendments. (*See, e.g.*, 2d Am. Compl. ¶¶ 3-4.) With respect to this claim, Plaintiffs allege that Defendants knew, "[w]ithin weeks of launch," that Provenge's "buy-and-bill" reimbursement structure was "causing concerns amongst physicians and thus inhibiting sales." (*Id.* ¶ 3.) Plaintiffs allege that Defendants concealed this fact from investors and deliberately misled investors by failing to disclose material facts. (*Id.* ¶¶ 3-7.) In particular, Plaintiffs allege that Defendants knew, but did not reveal to investors, that physicians were hesitant to prescribe Provenge because they were concerned about the high upfront cost to the physician and the uncertainty of being reimbursed. (*Id.*)

Plaintiffs make an effort to allege scienter for this claim. In their new complaint, they allege that the individual Defendants had numerous discussions with Dendreon's Board of Directors regarding physician reimbursement concerns. (*See, e.g.*, 2d Am. Compl. ¶ 3.) Plaintiffs argue that these discussions demonstrate knowledge of those concerns, and therefore scienter, i.e., an "intention 'to deceive, manipulate, or defraud.'" (Resp. at 17-24); *see Tellabs*, 551 U.S. at 313. Plaintiffs make the following specific allegations about discussions between Dendreon's Board and the individual Defendants:

- "At numerous board meetings held during the Relevant Period, Defendants and the Board discussed the facts that reimbursement concerns amongst physicians were 'significant', that physicians experienced 'reimbursement hassle and anxiety,' and that these concerns and anxieties were 'inhibiting Provenge's successful commercialization' and posed a 'significant downside' risk to revenues." (2d Am. Compl. ¶ 3.)
- "Over the course of numerous Board meetings in 2010 and 2011, Dendreon's senior management, including the Individual Defendants, presented reports to the Board that discussed the negative impact of reimbursement concerns on sales of Provenge, as well as reports that tracked cancellations of infusions due to concerns about reimbursement." (*Id.* ¶ 63.)
- In May, 2009, Dendreon presented a commercialization plan to its Board that outlined a strategy for streamlining reimbursement during the launch of Provenge. (*Id.* ¶ 69.)
- In June, 2009, Dendreon identified "Reimbursement Issues" as a potential downside risk of the Provenge launch, as well as "physician and patient response" and "payer response." (*Id.* ¶ 70.)
- In June, 2010, Defendants informed the board of several "key challenges," including "concern regarding cash outlays especially when multiple patients are being treated at a site without reimbursement history. . . . The Board also was informed that one of the 'key learnings' from the launch was that reimbursement

concerns are significant due to price (perceived concerns leading to caution)." (*Id.* ¶ 74.)

- In July, 2010, there was further discussion at a Board meeting regarding reimbursement concerns. (*Id.* ¶ 75.)
- "On September 14, 2010, the Board held another meeting, at which Dendreon's senior management made a critical presentation. . . . Importantly, by the time of the September 14 meeting, the Company had been tracking, for nearly a month, the number of infusions cancelled as a result of reimbursement concerns. The results of this tracking study that were presented to the Board were troubling. For example, in the week beginning August 8, 2010, 16 % of scheduled Provenge infusions were cancelled due to reimbursement-related issues. In their presentation, Dendreon's management identified reimbursement as a 'key issue' and informed the Board that 'reimbursement confidence is not yet fully established.'" (*Id.* ¶ 78.)
- "The Board was also presented with a sensitivity analysis . . . [concluding] that reimbursement issues could contribute to a 'significant downside' in revenues of more than $100 million . . . ." (*Id.* ¶ 79.)
- "The September presentation specifically noted the 'reimbursement hassle and anxiety,' and characterized the resolution of this issue as one of the 'critical success factors' for a successful Provenge launch." (*Id.* ¶ 80.) Similar information was repeated at a December 7, 2010 meeting. (*Id.* ¶ 82.)

- "On February 25, 2011, the Board held a special meeting . . . at [which] Defendant Gold discussed specifically 'challenges related to reimbursement.'" (*Id.* ¶ 83.)

Taken as a whole, these amendments do not make a compelling case for scienter. First and foremost, it is not compelling that Defendants identified physician reimbursement concerns to the Board, in a general way, as a "key challenge," a "downside risk," or other similar description. (*See* 2d Am. Compl. ¶¶ 3, 70, 74, 79, 80, 82.) Nor is it highly probative that Defendants had discussions with the Board about reimbursement concerns. (*See, e.g.*, *id.* ¶¶ 75, 83.) As everyone acknowledges, reimbursement was a major issue in the launch of Provenge. But there were many such issues. Defendants were monitoring developments related to reimbursement and updating the Board and investors of all new developments. None of Plaintiffs' new allegations tend to show that Defendants knew physician reimbursement concerns were more of a concern than they publicly acknowledged, let alone that they orchestrated a far-reaching fraud to cover up this fact.

If anything, Plaintiffs' new allegations suggest that there is no scienter. The new allegations suggest that Defendants knew physician reimbursement was important to Provenge's success. The allegations also suggest that Defendants had a plan to address physician reimbursement issues: namely, they would educate physicians about reimbursement, and they would obtain a favorable NCD, which, in theory, would all but resolve the reimbursement issue. (*See, e.g.*, *id.* ¶ 69.) Defendants had every reason to believe that a favorable NCD would substantially alleviate physician reimbursement concerns. Considering this, the new allegations support the inference that Defendants

believed they could address reimbursement concerns more than the inference that Defendants knew reimbursement concerns would cause their downfall and sought to cover up that fact.

Last, many of Plaintiffs' allegations are exaggerated, blown out of proportion, or taken out of context.[4] A good example of this is Plaintiffs' allegation that, during a week in August, 2010, "16 % of scheduled Provenge infusions were cancelled due to reimbursement-related issues." (*Id.* ¶ 78.) Further examination of this statistic reveals that it is misleading. In that particular week, six Provenge infusions were cancelled—only one of which was cancelled due to reimbursement concerns. (*See* 3/24/14 Wechkin Decl. Ex. 18 at 5.) Thus, only 16 % of *cancelled* infusions could be attributed to reimbursement concerns, not 16 % of all infusions. (*See id.*) Moreover, only a single infusion was actually cancelled for that reason. (*See id.*) Plaintiffs suggest that this demonstrates scienter because Defendants should have revealed this one infusion cancellation to investors but did not. (*See* 2d Am. Compl. ¶ 78.) This is not compelling, to say the least, and is typical of the type of inference Plaintiffs ask the court to draw.

Next, Plaintiffs allege that internal Dendreon reports demonstrate scienter. (*See id.* ¶¶ 4, 6.) In this regard, Plaintiffs present a number of internal "prescription vs. infusion" reports that they also referenced in their original complaint. (*See, e.g.*, *id.* ¶¶ 92-101.) They argue that these reports demonstrate scienter because they demonstrate

---

[4] Under the PSLRA, the court must weigh competing inferences and does not afford ordinary 12(b)(6) deference. *Watchguard*, 2006 WL 2038656, at *3. Thus, it is appropriate to examine Plaintiffs' allegations in detail rather than simply accept them as true. *See id.*

how supposedly declining prescription and infusion numbers would have tipped off Defendants that there was a major issue with reimbursement concerns.

There are several problems with this argument. First, Plaintiffs' allegations in this regard are not new. They were in the original complaint as well. Plaintiffs have not added any additional factual content to their internal report-related allegations, instead simply recasting these allegations in a new light. This is not helpful because the court already considered those allegations in ruling on the original motion to dismiss and found them insufficient to establish a compelling inference of scienter. (*See* 1/28/14 Order at 22-28.) Second, Plaintiffs ask the court to draw questionable inferences from the reports. It is not at all clear that Plaintiffs' allegations, even if taken in their most favorable light, lend any credence whatsoever to a conclusion that Defendants acted with intent to deceive, manipulate, or defraud. *See Tellabs*, 551 U.S. at 313. More often, Plaintiffs ask the court to take numbers out of context and assign to them a significance that is not readily apparent. (*See, e.g.*, 2d Am. Compl. ¶¶ 92-101.) The court will not do this. Third, there is nothing in the reports, and indeed nothing other than speculation, to suggest that any negative numbers Plaintiffs may be able to unearth from the internal reports are in any way attributable to or traceable to physician reimbursement concerns. In short, there is virtually nothing in the internal reports to suggest that Defendants knew that physician reimbursement concerns would be Dendreon's downfall and took active steps to cover up that fact.

Next, Plaintiffs seek to demonstrate scienter by showing that investors asked questions about physician reimbursement during conference calls. (2d Am. Compl.

¶¶ 72, 76, 77, 84.) This is not a compelling allegation even ignoring the fact that all of the questions paraded before the court in the Second Amended Complaint were in the record for the first motion to dismiss in this case as well. The fact that Defendants were asked questions by investors does not compel the inference that Plaintiffs suggest. Further, the documents before the court demonstrate that Defendants answered all of the questions in a responsive manner. Plaintiffs apparently seek to demonstrate that questions about physician reimbursement would have put Defendants on notice that reimbursement was a concern. This is a far-fetched inference at best, and the court does not find it compelling.

Plaintiffs next allege that confidential witnesses can attest to factual content tending to show scienter. (2d Am. Compl. ¶¶ 104-08.) As above, however, this is simply a rewriting of allegations that the court already considered when examining the original complaint. Plaintiffs do not present anything new with respect to confidential witnesses that would warrant a different result on this motion.

Last, Plaintiffs point to several internal surveys as evidence of scienter. Specifically, Plaintiffs allege that Defendants shared certain survey results with the Board that showed how grave a concern the physician reimbursement issue was:

- On March 9, 2011, "Defendant Bishop informed the Board that, of the potential Provenge providers that were surveyed, more than 65 % had medium or low confidence that they would be reimbursed if they prescribed Provenge to one of their patients. Bishop also advised the Board that over 14 % of providers that had

performed a Provenge infusion in 2010 had not yet scheduled an infusion in 2011 because of reimbursement concerns or errors." (2d Am. Compl. ¶ 85.)

- On June 22, 2011, "Defendant Bishop informed the Board that issues pertaining to reimbursement represented a constraint on Provenge's sales. With respect to reimbursement, Defendant Bishop specifically stated that 'customers lack confidence, and fear of denial is a major break on sales.' In addition, approximately 45 % of the oncologists and urologists the Company surveyed 'strongly agreed' that their practices could not afford to advance the cost of Provenge pre-reimbursement. Bishop characterized the reimbursement issues as 'critical.'" (*Id.* ¶ 87.)
- On July 28, 2011, "the Board was told that 'most health care providers (75 %) still view Provenge reimbursement as onerous' and that 'factors relating to reimbursement are the largest barriers to Provenge usage.'" (*Id.* ¶ 88.)

Unlike the allegations discussed above, these allegations are probative of scienter. They suggest that Defendants knew about physician reimbursement concerns before they publicly revealed those concerns. (*Id.* ¶¶ 85, 87, 88.) These surveys are consistent with Plaintiffs' theory that Defendants intentionally hid information from the public.[5] That

[5] On the other hand, the surveys are also consistent with a more benign inference—that Defendants were learning about the effect of physician reimbursement concerns as information pertaining to those concerns became available, and that they shared that information with the public only when it became appropriate to do so. The timing of the surveys, in particular, supports this more benign inference. Most of the surveys were presented to the Board just before Dendreon's August 3, 2011, revelation that physician reimbursement concerns were a major factor limiting Provenge's success.

said, the surveys are only one allegation to be considered in the court's holistic analysis of scienter. As explained in more detail below, this allegation is not enough to tip the scales in Plaintiffs' favor.

In sum, Plaintiffs' amendments with respect to physician reimbursement do not paint a compelling picture of scienter. The additions alter the nature of the complaint somewhat but do not make major substantive changes of the kind needed to change the outcome from the first motion to dismiss.

2. Capacity Constraints

The second point of emphasis in the new complaint is Defendants' statements pertaining to capacity constraints. During the relevant period, Defendants made multiple references to the fact that Dendreon was "capacity constrained," i.e., unable to meet the total demand for Provenge that existed in the marketplace. Plaintiffs allege that Defendants were not, in fact, capacity constrained, that they knew they were not capacity constrained, and that they deliberately misled investors into thinking they were capacity constrained in order to draw attention away from Dendreon's lackluster sales performance. (2d Am. Compl. ¶¶ 115-30.)

However, Plaintiffs allege virtually no new facts in connection with this claim. For the most part, Plaintiffs simply recast the allegations in their previous complaint without adding any substantive content. (*See id.* ¶¶ 117-23.) For example, they allege that "Defendants repeatedly deflected attention from the discrepancy between Dendreon's actual results and investors' expectations by pointing to the Company's 'ramp-up' of production, and attributing Dendreon's underperformance to the fact that

the Company was 'capacity constrained.'" (*Id.* ¶ 117.) There were substantively similar allegations in the old complaint as well. (*See, e.g.*, Am. Compl. ¶ 78, 83, 88-89.) This is true of most of Plaintiffs' allegations related to capacity constraints. Indeed, there are no capacity-constraint allegations in the new complaint that demonstrate a strong inference of scienter where there was not one before.

There is one possible exception. Plaintiffs allege that "[a]t Dendreon's December 7, 2010 Board meeting, the Individual Defendants met with the Board and discussed the fact that the Company had not been utilizing its full manufacturing capacity since the launch of Provenge." (2d Am. Compl. ¶ 132.) If true, this would be consistent with Plaintiffs' narrative of fraud. Standing alone, however, it does not alter the outcome of this second motion to dismiss or the court's assessment of scienter. As explained in more detail below, this fact is not enough to tip the balance of the court's holistic scienter analysis in Plaintiffs' favor.

3. "On-track" Statements

The third major feature of the Second Amended Complaint is its focus on "on-track" statements. Again, Plaintiffs' amendments attempt to focus attention on these claims and provide more detail with respect to scienter. Plaintiffs' "on-track" claims are premised on the notion that Defendants knew early after Provenge's launch that they would not meet their revenue targets and other forecasts: "As the company's Board minutes and internal reports reflect, the Company had deviated off track by the end of 2010. Due to their reimbursement concerns, medical supply centers simply were not prescribing and treating patients in enough numbers to allow Defendants to meet their

ambitious targets." (*See, e.g.*, 2d Am. Compl. ¶ 9.) Plaintiffs point to several statements made during investor conference calls where Defendants indicated that they were "on track" to meet their revenue guidance and patient treatment forecasts. (*Id.* ¶¶ 147, 151.) Plaintiffs allege that Defendants knew all along they would not meet these targets and defrauded investors by telling them they were on track to do so. (*See, e.g.*, *Id.* ¶ 9.)

Most of Plaintiffs' amendments with respect to this claim have no bearing at all on scienter. In fact, most of them simply highlight the actual on-track statements made by Defendants:

- On August 3, 2010, Dendreon issued a press release stating that "Dendreon is on track to provide Provenge to approximately 2,000 patients over the first 12 months of the launch and to date has already received prescriptions from more than 500 patients." (*Id.* ¶ 147.)
- March 1, 2011, Defendant Mr. Gold stated that: "We are on track with providing Provenge to approximately 2,000 patients by the end of July." (*Id.* ¶ 151.)
- Defendants "repeatedly assured investors that the Company was hitting [key] guideposts" along the way to meeting its revenue guidance. (*Id.* ¶ 159.)
- Defendant Schiffman stated in April, 2011 that Dendreon was "hitting [its] guidance." (*Id.* ¶ 163.)

These statements do not indicate scienter at all. Nothing about them in any way suggests that Defendants knew that the statements were false or misleading, let alone that they had an intent to "deceive, manipulate, or defraud." *See Tellabs*, 551 U.S. at 313.

Other amendments are equally unhelpful. Plaintiffs focus on the fact that analysts asked questions about revenue guidance and other forecasts during conference calls and that, at one point, Defendant Gold "artfully deflected" an analysts' question regarding January sales numbers. (2d Am. Compl. ¶¶ 141-42, 161.) As discussed above, it does not demonstrate scienter to point out that analysts asked questions about a topic. It merely shows that it was a point of interest for investors. Plaintiffs ask the court to make an inference of scienter from these questions, but this inference is too far-fetched, and the court will not make it. The reference to Mr. Gold's "artful deflection" is also off-base. The exchange in question was rather unremarkable:

> **Rachel McMinn - Bank of America Merrill Lynch:** Are you disclosing January sales?
>
> . . .
>
> **Mitchell H. Gold, M.D., President and CEO:** Rachel, we gave guidance for the year which is $250 million to $400 million for the year which we expect approximately half of that will occur in the fourth quarter of this year. In addition, for the first quarter, we said that we are still in a capacity constraining environment and our peak capacity is $9 million to $10 million a month and that's what you should expect in terms of revenue for Q1.

(3/24/14 Wechkin Decl. Ex. 5 at 10.) It requires highly creative thinking to infer from this exchange that Defendants knew they were going to miss their sales targets in March, 2011, let alone before that time, and further that they took steps to illegally conceal that fact from the public. The court is not required to, and will not, indulge this inference. *See In re Gilead Sciences*, 536 F.3d at 1055. Finally, many of Plaintiffs' amended allegations simply repeat patterns described above—either recasting allegations made in

the original complaint without adding any substantive content, or else making generalized, non-specific allegations of wrongdoing that the court is not required to accept as true. (*See, e.g.*, 2d Am. Compl. ¶¶ 9, 109-10, 151-54, 173-78); *In re Gilead Sciences*, 536 F.3d at 1055. Neither of these tends to show that there is any greater likelihood of scienter than there was when the court examined the previous motion to dismiss.

E. Holistic Analysis

Just as before, Plaintiffs' complaint fails to adequately allege a strong inference of scienter. In ruling on the previous iteration of this motion, the court undertook a rigorous analysis of the scienter question. The court concluded that there were two inferences that could be reasonably drawn from the facts—the malicious one advanced by Plaintiffs that involved fraud, and the benign one advanced by Defendants that involved misjudgment. (1/28/14 Order at 23-24.) The court then examined both inferences as required by the PSLRA, and concluded that the malicious inference was "significantly less compelling" than the benign inference. (*Id.* at 24-25.) The specific reasons for this can be found in the prior order and will not be repeated here. (*See id.* at 25-28.) The court has now analyzed the scienter question based on the facts alleged in the Second Amended Complaint, and concludes that the new complaint suffers from the same problems as the old complaint.

The analysis is a holistic one. *See Zucco*, 552 F.3d at 991-92. As the Ninth Circuit has held, a holistic approach is necessary and a "segmented analysis" is not adequate. *Id.* Rather, the court must consider the totality of the circumstances and

determine whether the allegations of scienter, in light of the entire record, is "as cogent or as compelling as an opposing innocent inference." *Id.* Thus, no one reason, consideration, or factor determines the outcome of the court's analysis.

The analysis is also a stringent one. As mentioned above, to satisfy the PSLRA's rigorous pleading standards, the plaintiff must allege facts that give rise to a "strong inference" of scienter—that is, an inference that is "cogent and at least as compelling as any opposing inference of nonfraudulent intent." *Tellabs*, 551 U.S. at 314, 324 (quoting *Ernst*, 425 U.S. at 194). The court must weigh all competing inferences that may be drawn from the facts and can "only allow the complaint to survive a motion to dismiss if the malicious inference is at least as compelling as any opposing inference." *Zucco*, 552 F.3d at 991. Under this standard, a "Rule 10b-5 claim does not receive the traditional deference a court affords a complaint in resolving a motion to dismiss for failure to state a claim." *Watchguard*, 2006 WL 2038656, at *3.

Plaintiffs' Second Amended Complaint does not pass muster under the PSLRA. As explained above, most of Plaintiffs' new allegations are unhelpful. Many of them simply recast factual allegations made in the previous version of the complaint. Others do nothing to demonstrate scienter. There are clearly several new allegations in the Second Amended Complaint that are consistent with an inference of scienter (*see, e.g.*, 2d Am. Compl. ¶¶ 85, 87-88, 132), but on balance these are not enough to persuade the court that the malicious inference is "at least as compelling" as the benign inference. The new allegations do not substantially tip the scales in Plaintiffs' favor.

F. Ancillary Claims

All of Plaintiffs' ancillary securities claims fail for the same reasons described in the court's prior order. (1/28/14 Order at 28); *Lipton v. Pathogenesis Corp.*, 284 F.3d 1027, 1035 n.15 (9th Cir. 2002) ("[T]o prevail on their claims for violations of § 20(a) and § 20A, plaintiffs must first allege a violation of § 10(b) or Rule 10b-5."). Specifically, Plaintiffs' insider trading claims fail because Plaintiffs do not plead a strong inference of scienter. Thus, dismissal of these claims is appropriate just as it was before. The court GRANTS Defendants' motion to dismiss all federal securities law claims in this case.

G. State Law Claims

Defendants make a cursory argument that, this time around, the court should also dismiss Plaintiffs' state law claims. (Mot. at 33-34.) Defendants' argument consists of a single paragraph and does not raise any novel points that the court did not consider in its analysis of the first motion. (*See id.*) As such, the court DENIES Defendants' motion to dismiss Plaintiffs' state law claims.

H. Leave to Amend

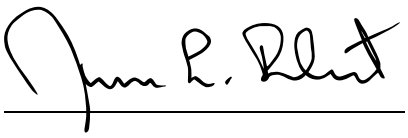
The court is hesitant to grant leave to amend yet again, as it appears that further amendments may be futile. On the other hand, leave to amend must be granted with "extreme liberality" in securities cases. *Eminence Capital, LLC v. Aspeon, Inc.*, 316 F.3d 1048, 1052 (9th Cir. 2003) (reversing denial of leave to amend even though complaint had been amended three times already). As such, if Plaintiffs wish to amend their complaint, they are permitted to file a motion for leave to amend within 20 days of the

date of this order. The motion should attach any proposed amended complaint, which must comply with the formatting instructions described in W.D. Wash. Local Rule LCR 15.[6] The motion should also cite relevant authority explaining why leave to amend is appropriate. If necessary, the motion and the proposed amended complaint may be filed under seal consistent with the court's prior orders in this case.

IV. CONCLUSION

For the foregoing reasons, the court GRANTS in part and DENIES in part Defendants' motion to dismiss (Dkt. # 61).

Dated this 5th day of June, 2014.



JAMES L. ROBART
United States District Judge

[6] In other words, Plaintiffs must indicate in the amended complaint "how it differs from the pleading that it amends by bracketing or striking through the text to be deleted and underlining or highlighting the text to be added." *See* W.D. Wash. Local Rule LCR 15.